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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/045,937

10/19/2001

David J. Beebe

282.020

4878

23598

7590

06/27/2006

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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/045,937

Applicant(s)

BEEBE ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10, 13-29 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 13-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

In response to the 3/23/06 Pre-Appeal Request for Review, it was determined a new ground of rejection should be made.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 13-29 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 18 are vague and indefinite what is intended by a “pregel”. Is the “pregel” the same as the “pre-polymer mixture”? These claims are also not clear what steps are required to accomplish the “polymerizing”.

Claim 10 is vague and indefinite what is intended by “... the monitor structure generates ... having a predetermined value” and how this language further limits the method claims.

Claims 13-15 are dependent upon canceled claim 12.

Claims 13 and 21 are not clear what steps are required to accomplish the claimed “cleaning the channel) (e.g. is the cleaning accomplished by a solvent, water , air ?) and. “polymerizing”.

Claim 17 is not clear where the second monitor structure is in comparison to the first .

Claim 19 is not clear what steps are required to accomplish the claimed “immobilization”.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 29 and 31-36 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by McDewitt et al. (2003/0064422).

McDewitt et al. teach a multi-analyte detector. Paragraphs [0123], [0127] and [145] teach a swelling polymer particle with an indicator attached thereto. Paragraph [154] teaches phenolphthalein and congo red indicators can be attached to the particle.

Claims 29 and 31-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tiru et al. (USP 4,149,852).

Tiru et al. teach a thermochromatic composition comprising more than one pH indicator to indicate a thermal history of a product. Column 2 teaches the pH composition will be in a frozen state which has been read on the claimed change in change from a first dimension to a second dimension. Table 2 teaches the claimed indicators phenolphthalein and congo red.

Claims 10,13-15, 18-23-24, 28-29 and 31-34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Beebe et al. (USP 6,488,872).

Beebe et al. teach a microfluidic device substantially as claimed comprising a microfluidic device with channels containing a polymer gel that is a pH sensor/actuator(10) that will expand or contract based upon the sensed pH. Column

24, 26 and 30 lines 12+, 40 and 42+ respectively teach mixing a pH indicator/ dye, such as phenolphthalein with the polymer gel. This has been read on the claimed "mixing a dye in a pre-polymer mixture and providing the same as a pregel". Additionally, the taught gel has also been read on the claimed "monitor structure change dimensions ...".

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 25 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beebe et al. (USP 6,488,872).

See the appropriate paragraph of the 1/26/05 final Office action for the teachings of Beebe et al.

Beebe et al. is silent to the use of the claimed congo red pH indicator.

It is notoriously well known in the art that congo read and phenolphthalein are equivalent pH indicators (see McDewitt et al. and Tiru et al. supra.).

It would have been within the skill of the art to modify Beebe et al. and use an equivalent pH indicator to phenolphthalein, such as congo red, as selection of a material based upon its suitability of intended use (see *In re Leshin*, 125 USPQ 416).

***Allowable Subject Matter***

Claims 17 and 26-27 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art fails to teach a device with a second monitor structure that gives a visual display in response to a second parameter in the fluid.

***Response to Arguments***

Applicant's arguments filed 3/23/06 have been fully considered but they are not persuasive.

Applicants' state the instant invention "generates a visual display independent ....". In light of the above 35 USC 112 second paragraph rejections, it is not understood by this argument.

Applicants' remarks directed to McDewitt et al. and Tiru et al. to claims 10 and 13-28 were convincing. However, the 3/23/06 remarks were not commensurate in scope with claims 29 and 31-36.

Applicants' state Beebe et al. does not teach mixing a dye into a pre-polymer mixture. Beebe et al. teach in columns 24, 26 and 30 lines 12+, 40 and 42+ respectively teach mixing a pH indicator/ dye, such as phenolphthalein with the polymer gel. This has been read on the claimed "mixing a dye in a pre-polymer mixture and providing the same as a pregel".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander  
Primary Examiner  
Art Unit 1743